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Variability in Measurement of Internal Carotid Artery Stenosis by Arch Angiography and Duplex Ultrasonography – Time for a Reappraisal?

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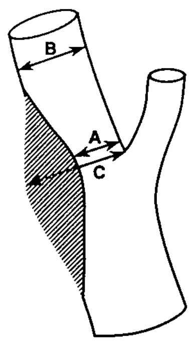
Objectives: *to determine the inter- and intra-observer variability of ICA stenosis measurement using duplex, ECST and NASCET methods.*
Design: *a retrospective review of arch angiograms and carotid duplex scans in 50 patients.*
Materials and methods: *carotid stenoses were calculated by three independent observers according to NASCET and ECST methods. Variation between observers for NASCET and ECST was determined. For each observer, the variation between NASCET and ECST was determined. The variation between duplex and both NASCET and ECST was determined.*
Results: *inter-observer agreement on the degree of ICA stenosis was clinically and statistically good for NASCET but was poorer for ECST. For each observer, comparison between NASCET and ECST showed 95% limits of agreement of around 50 percentage points. Comparison of duplex with NASCET and ECST showed similar 95% limits of agreement.*
Conclusions: *arch angiography allows reproducible measurement of carotid stenosis by the NASCET method between different observers. For the ECST method, reproducibility is not so good. Variations in results between NASCET and ECST and between angiography and duplex are significant. In view of the similar results of the NASCET and ECST trials, this suggests that degree of stenosis may only be a surrogate marker for outcome following carotid endarterectomy.*

Key Words: Internal carotid artery stenosis; Arch angiography; Carotid duplex scanning.

Introduction

The European Carotid Surgery Trial[1] (ECST) and the North American Symptomatic Carotid Endarterectomy Trial[2] (NASCET) both confirmed that symptomatic patients with a 70% or greater stenosis of the ipsilateral internal carotid artery benefit from carotid endarterectomy (CEA). Both studies were based on the measurement of internal carotid artery (ICA) stenosis by selective carotid angiography. However, each trial used a different method of measurement of the stenosis (Fig. 1). Reproducibility of ICA stenosis measurement by selective carotid angiography has been shown to be good,[3] and the relationship between the ECST and NASCET techniques has been demonstrated.[4–7]

However, the risk of stroke associated with selective carotid angiography[8,9] has led to many centres basing their decisions to perform CEA on arch angiography or duplex ultrasonography.[10] Arch angiograms give less clear views of the ICA origin than do selective angiograms, making the measurement of a stenosis more prone to error.[11] Duplex ultrasonography measures the degree of stenosis using entirely different criteria to angiography.[12] These factors have led us and others[13,14] to question the reproducibility of arch angiographic measurement of ICA stenosis and the level of agreement between arch angiography and duplex ultrasonography.



ECST method: $\frac{C-A}{C}$ x 100% stenosis

NASCET method: $\frac{B-A}{B}$ x 100% stenosis

Fig. 1. ECST and NASCET methods for assessing carotid stenosis.

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The aims of this study were:

(1) to determine the inter-observer variability in the measurement of ICA stenosis on arch angiography using the ECST and NASCET methods;
(2) to determine intra-observer variability between the ECST and NASCET methods in the measurement of ICA stenosis on arch angiography;
(3) to compare duplex measurement of ICA stenosis with arch angiographic measurement by ECST and NASCET methods.

Methods

Fifty consecutive patients were investigated for transient cerebral or occular ischaemia by arch angiography and duplex ultrasonography.

Angiographic measurements

Intra-arterial digital subtraction angiographic (DSA) images of the carotid vessels of 50 patients (100 carotid bifurcations) were retrospectively reviewed. Angiography was carried out on a V3000 dedicated angiographic unit (Philips, Eindhoven) with a 5F pigtail catheter placed in the ascending aorta. Views of each carotid were taken at 35° to the sagittal antero-posterior plane with the head turned to the side and further oblique or AP views were obtained as necessary. The degree of ICA stenosis was measured from the hard copy laser film images using callipers. The degree of stenosis was calculated according to both the ECST and NASCET methods (Fig. 1).

The calculated stenosis was expressed in the following manner:

(1) inter-observer comparison – into four bands (<30%; 30–69%; 70–99% and occlusions);
(2) intra-observer comparison – as the actual percentage narrowing of the vessel lumen.

Deciles were not used for the inter-observer comparisons as they have been previously shown to result in wide discrepancies.[15]

Three observers made the measurements: (1) a Consultant Vascular Radiologist (RA); (2) a Senior Radiological Registrar experienced in angiography (RR) and (3) a Senior Vascular Surgical Registrar (GG). Each observer made the observations independently with no reference being made to the other observers' results. Each observer measured all the study films firstly by the NASCET method. A month later the films were randomly placed in a different order and each observer independently measured the stenoses by the ECST method, without any reference to the NASCET results. In this way, blinded measurement by the two techniques and between observers was ensured.

Duplex measurement

All Duplex examinations were performed by the same experienced accredited vascular technologist (AF) using an ATL Ultramark UM9 or HDI scanner (Advanced Technical Laboratories) with a 5 MHz or 7.5 MHz linear array pulsed Duplex transducer. No reference was made to the angiographic measurements. Strandness' criteria, modified to allow grouping into the four bands as above, were used to measure the degree of stenosis.[12] These criteria classify the degree of stenosis by the peak frequency of the spectrum, the degree of spectral broadening and the end diastolic frequency. The duplex measurements were compared with the DSA stenosis as measured by Observer 1. Duplex was compared with the angiographic measurements made by the most experienced angiographic observer in order to replicate clinical practice.

Statistics

Inter-observer variation of DSA measurements (comparisons between observers for NASCET and ECST) was assessed using kappa (κ) values for correlation between observers. A kappa score of greater than 0.75 was taken to demonstrate excellent agreement, a score of 0.4 to 0.75 as being fair to good and one of less than 0.4 as showing poor agreement.[16]

Intra-observer variation of DSA measurements (NASCET compared to ECST for each observer) and the variation between DSA and Duplex was assessed by Bland-Altman[17] plots. These indicate graphically the variability between two methods of measuring the same phenomenon. The arithmetic difference between the two measures is plotted against their mean. If agreement were complete all points would be on the zero line of the *y*-axis and the 95% confidence intervals would be very tight. The greater the spread from the zero line the greater the discrepancy. The bias is calculated to give an indication of the extent by which one measurement method consistently over- or underestimates compared to the other.

Table 1. Interobserver agreements of carotid stenosis.

(a) Observer one and observer two using the NASCET system of measurement (kappa = 0.70)

	% Stenosis	Observer two				
		<30	30–69	70–99	100	Total
Observer one	<30	31	8			39
	30–69	3	16	4		23
	70–99		6	19		25
	100			1	12	13
	Total	34	30	24	12	100

(b) Observer one and observer two using the ECST system of measurement (kappa = 0.66)

	% Stenosis	Observer two				
		<30	30–69	70–99	100	Total
Observer one	<30	24	2			26
	30–69	13	21	1		35
	70–99	1	7	18		26
	100			1	12	13
	Total	38	30	20	12	100

Table 2. Comparison between observers in the selection of patients for surgery.

(a) Observer one and observer two using the NASCET system of measurement (kappa = 0.70)

		Observer two		
		Surgery	No surgery	Total
Observer one	Surgery	19	6	25
	No surgery	5	70	75
	Total	24	76	100

(b) Observer one and observer two using the ECST system of measurement (kappa = 0.72)

Operative classification		Observer two		
		Surgery	No surgery	Total
Observer one	Surgery	18	8	26
	No surgery	2	72	74
	Total	20	80	100

Results

Twenty-seven males and 23 females were studied with a mean age of 66.7 years (45–82 years).

Arch angiography

Inter-observer variability

NASCET. All three observers agreed that 12 carotid bifurcations were normal and that 12 internal carotid arteries were occluded. For the remaining 76 arteries, the range of measured stenoses were reviewed. The maximum range of measurement was 47 percentage points with a mean of 17 (s.d. = 12). When the percent stenoses were graded into the four bands, agreement between Observers 1 and 2 and between Observers 2 and 3 was "fair to good" (kappa = 0.70 and 0.67 respectively) and agreement between Observers 1 and 3 was "excellent" (kappa = 0.77). Table 1(a) illustrates agreement between Observers 1 and 2.

We also compared each pair of observers to determine the incidence of variability in the selection of potential patients for surgery (i.e. 70–99% stenoses). Kappa agreement was "fair to good" for all pairs of observers (Observers 1 and 2, kappa = 0.70; Observers 1 and 3, kappa = 0.72; Observers 2 and 3, kappa = 0.63). Table 2(a) illustrates agreement between Observers 1 and 2.

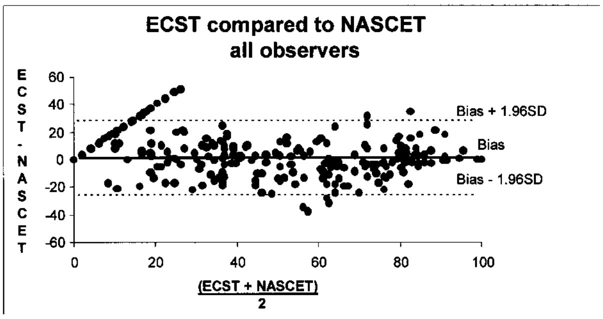
ECST. All three observers agreed that 12 internal carotid arteries were occluded and four bifurcations were normal. For the remaining 84 arteries, the range of actual stenoses were reviewed. The maximum range of measurement was 61 percentage points with a mean of 21 (s.d. = 11). After grading the stenoses into the four bands, the interobserver agreement as measured by the Kappa statistic was in the "fair to good" range for all pairs of observers (Observers 1 and 2, kappa = 0.66; Observers 1 and 3, kappa = 0.63; Observers 2 and 3, kappa = 0.58). There was a non-significant trend for the Kappa statistic to be lower than in the NASCET comparisons. Table 1(b) illustrates agreement between Observers 1 and 2.

The allocation of stenoses to the surgically important 70–99% band was also compared. The Kappa statistic was in the "fair to good" range for all pairs of observers (Observers 1 and 2, kappa = 0.72; Observers 1 and 3, kappa = 0.56; Observers 2 and 3, kappa = 0.49) but there was again a non-significant trend to worse agreement than with the NASCET measurements. Table 2(b) illustrates agreement between Observers 1 and 2.

Intra-observer agreement

Intra-observer variability between the two angiographic measurement techniques was assessed using the actual measured degree of stenosis and Bland–Altman plots.

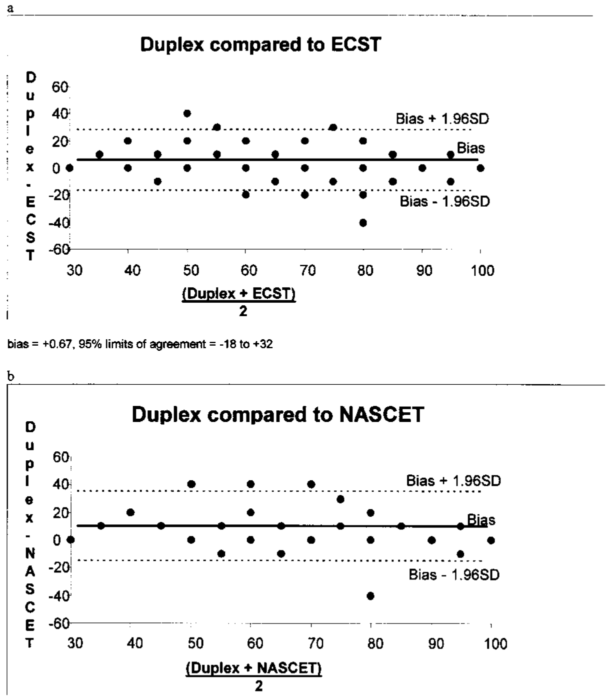
The results are presented for all observers grouped



bias = +1.93, 95% limits of agreement =-24 to +28

Fig. 2. Bland–Altman plot comparing ECST with NASCET for all observers.

together (Fig. 2). The linear series of points is due to eight stenoses being classified as "normal" by NASCET and as being between 10% and 30% by ECST. These recordings apart, the spread between the methods is seen to be fairly uniform across the whole range of stenoses. The 95% limits of agreement show that 95% of ECST measurements were within approximately 50 percentage points of NASCET measurements. The "operative misclassification" rate (disagreements on the 70–99% band) was 8.3% (95% CI: 4% to 15%).



bias = +0.98, 95% limits of agreement = -16 to +36

Fig. 3. (a) Bland–Altman plot comparing ECST with Duplex; (b) Bland–Altman plot comparing NASCET with Duplex.

Duplex compared to arch angiography

The Duplex measurements were compared to the angiographic observations made by Observer 1. A wide variability between Duplex and ECST and NASCET measurements was demonstrated using Bland-Altman plots (Fig. 3a,b). The 95% limits of agreement were similar to those between NASCET and ECST measurements for individual observers (around 50 percentage points). Operative misclassification between Duplex and angiography was high. For ECST the misclassification rate was 19% (95% CI: 12%–28%), while for NASCET it was 21% (95% CI: 14%–31%) with duplex resulting in higher degrees of stenosis than ECST or NASCET.

Discussion

Reproducibility of measurement of carotid stenosis is important in the clinical management of patients, in the prediction of morbidity and in the comparison of results from different centres. Selective carotid angiography is still regarded as the "gold standard", not only because the visual image it produces is easier to interpret by both radiologist and surgeon, but principally because the ECST and NASCET trials used this modality. Duplex scanning is, however, increasingly being used as the main imaging modality prior to surgery. The degree of reproducibility between observers and between measurement methods therefore requires quantification.

We analysed inter-observer variability of NASCET and ECST measurements by applying κ values interpreted according to the Landis and Koch guidelines.[16] There was complete agreement between all observers using both NASCET and ECST criteria when examining normal or occluded internal carotid arteries. Interestingly, however, the NASCET criteria suggested that 12 internal carotid arteries were normal while only four were normal by ECST criteria. This suggests that the carotid bulb extrapolation of the ECST method has a tendency to be made too wide – a fact which is supported by the ESCT-measured stenoses being consistently higher than NASCET-measured stenoses. While there was statistically good correlation in the four bands of stenosis, particularly when identifying those patients who may benefit from surgery, there remained a worryingly large proportion of patients where this correlation was not achieved. This lack of correlation (which was higher using the ECST criteria) was 10% between the most experienced observers and increased slightly as observer experience fell. Barnett *et al.*[18] indicated that overestimation of carotid stenosis leads to surgical treatment that is unnecessary. The converse is also true in that an underestimate of the stenosis may lead to conservative treatment where surgery is more beneficial.[19] It is therefore important that clinical decisions are based on one experienced observer's reading of the angiogram within each unit to minimise variations in clinical practice.

The ECST method of measuring ICA stenoses is known to result in higher degrees of stenosis when compared to the NASCET method. The relationship between the two methods has been established[4–7] but this depends on how the carotid bulb is extrapolated and on where the distal ICA measurement is made. Studies comparing different measurement techniques are also carried out with varying degrees of rigour. Criteria have recently been suggested for future comparative studies.[20] The final reports from NASCET[21] and ECST[22] confirm the agreement in their initial reports, allowing for the differences in stenosis measurement. ECST recommend that stenoses greater than 80% (corresponding to 60% by NASCET) should be considered for surgery. The final NASCET report cautiously recommends surgery for stenoses greater than 50% (corresponding to 75% by ECST) in selected patients and selected centres. The degree of intra-observer variability which we found when comparing NASCET with ECST (Fig. 2) confirms the dangers of simple numeric comparison between the two methods.

There are several other reasons for the discrepancy between NASCET and ECST. The NASCET method of measuring ICA stenosis is inherently more reproducible than the ECST method, as the width of the distal ICA is easier to measure than an extrapolation of the carotid bulb (Fig. 1). However, there is no fixed reference point for measuring the width of the distal ICA using NASCET, so it is likely each observer will measure at a different point. The NASCET method will also give a negative result for minor degrees of stenosis if the distal ICA is small. Our results show a trend towards the greater inter-observer reproducibility of the NASCET method and show approximately the same variation between observers as in other reports.[23] The carotid stenosis index (which compares the narrowest width of the stenosis with the distal healthy common carotid artery diameter) has this same advantage as NASCET in terms of reproducibility but was not studied in this work. It has subsequently been suggested[23] that this method should be adopted as the standard method for measurement of carotid stenosis, even though it has not been assessed in the same way as the NASCET and ECST criteria. The NASCET investigators do not agree with its use, however.[24]

The image quality of carotid angiograms is generally better with a selective carotid injection than with an aortic arch injection. Two views are measured on each artery and the maximum stenosis takes both views into account. Plaque is often eccentric and a single view may markedly underestimate the stenosis if it is projected *en face*. This is a problem with arch studies as vessel overlap may be seen on some of the projections. This may be expected to result in better inter-observer agreement when a selective injection is used. However, there is conflicting evidence on this point. One study has shown very high kappa scores (kappa = 0.77, excellent agreement) for inter-observer variability on selective angiography using NASCET criteria.[3] Another report[25] using ECST criteria showed lower scores, as may be expected, but there was little difference between the inter-observer variability on selective angiography (kappa = 0.68, fair to good agreement) compared to arch angiography (kappa = 0.64, fair to good agreement). Our results are similar to these reports. Difficulty persists with those patients whose measured stenosis falls in the 60–80% range, around the cut-off point for surgery. Selective injections do have a greater risk of major disabling stroke[8,9] and therefore should be avoided if possible. We feel they should be limited to studies where the carotid bifurcation cannot be seen adequately on arch views or if the measured stenosis is close to 70% when there is doubt whether to proceed to surgery.

A further discrepancy could be due to the indistinct margin of the arterial edge on DSA as noted by Gagne.[3] This may be improved by selective injections or by printing larger images on the film. Our images were printed on a 16 cm by 13 cm sized frame and printing the images on a larger frame may result in a smaller discrepancy in the measurement. All our images were DSA and it has been suggested that this can affect inter-observer error.[3] Our study was performed retrospectively, measuring the laser film with callipers accurate to 0.02 mm. A future prospective study could determine whether the use of edge detection software could reduce inter-observer error.

Bland–Altman plots showed the spread between ECST and NASCET measurements for each observer to be fairly even across the whole range of stenoses, with perhaps slightly less variation as the stenosis exceeds 90%. What is important is the width of the 95% limits of agreements – the range within which 95% of the ECST minus NASCET estimates will fall. For all observers this covered a spread of around 50 percentage points. Put another way, 95% of ECST estimates were within 50 percentage points of the NASCET estimate of the degree of stenosis – there is a significant difference in the result of the two techniques.

In comparison with the differences between ECST and NASCET, the differences between Duplex assessment and angiography are real and clinically significant, with duplex assessed stenoses being tighter than either ECST or NASCET. The Bland–Altman plots (Fig. 3) demonstrate the variability across the lower degrees of stenosis, although there is a trend towards convergence as the stenosis exceeds 80%. Again, the 95% limits of confidence covered a spread of around 50 percentage points of degree of stenosis – not dissimilar to reports from other groups.[26] In contrast to the intra-observer angiographic comparisons, however, levels of agreement did not become acceptable as the clinically relevant bands and "operative misclassifications" were compared. The "operative misclassification" rate of 20% is of real concern, with 1 in 5 patients being potentially incorrectly assigned by duplex, if we are to take angiography as the gold standard. Other work has implied that Duplex ultrasound may be more accurate in assessing the degree of stenosis than angiography.[27–29]

Clearly, duplex measures the stenosis in an entirely different way to angiography so differences could reasonably be expected. Furthermore, the actual criteria used to determine the degree of stenosis on duplex are being re-examined.[30–39] This process may result in closer agreement between angiography and duplex. It is also important to realise that a stenosis in the contralateral internal carotid artery can affect duplex measurement of the index side,[40] a phenomenon not encountered in angiography. Additionally, interobserver and interlaboratory variation in duplex measurement has been documented.[41–43] Patients may be advised to have surgery following duplex scanning when their stenoses are not in fact as tight as may be demonstrated on angiography. It may be that duplex should be used as a screening tool, reserving angiography for those with significant stenoses.[13,44]

There is no right or wrong method of measuring the degree of carotid stenosis – each technique simply examines a different aspect of the same phenomenon. Furthermore, there is no "gold standard" (including the measurement of surgical specimens) other than selective angiography, for this technique alone has been correlated to clinical outcome. However, the discrepancy between ECST and NASCET methods suggests there may be factors other than the simple degree of stenosis resulting in a correlation between ICA disease and clinical outcome. Duplex gives a more physiological measurement of the degree of stenosis and, as is being currently studied (Nicolaides. Asymptomatic carotid stenosis and risk of stroke (ACSRS). The IUA natural history multi-centre study for identification of a high risk group. St. Mary's Hospital, U.K.), provides information on plaque composition – something which may be equally, or more, important as degree of stenosis in determining prognosis. Perhaps the time has come to examine which combination of techniques will identify those carotid plaques that should be treated by surgery. In the meantime, surgeons should be clear about the measurement method used and its relationship to the proven techniques of ECST and NASCET.

Although our results have shown satisfactory clinically relevant correlation between observers of different experience and speciality, there was discrepancy across all degrees of stenosis. Further work is needed to determine the accuracy of arch angiography. Correlation with duplex was poor. Each unit using duplex to select patients for carotid endarterectomy should consider formal comparison of their duplex results with angiography. Angiographic measurements should be made by experienced observers and in any one unit a very limited number should perform this task to minimise variation in clinical practice.

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